

International Warehouse Logistics Association

1629 13 0117 1053

June 9, 2006

Office of Information and Regulatory Affairs
U.S. Office of Management and Budget
Attn: Stuart Shapiro
Desk Officer for the Food and Drug Administration

Re: Docket No. 02N-0277

Dear Mr. Shapiro:

The International Warehouse Logistics Association (IWLA) welcomes this opportunity to submit comments with regard to the data collection requirements of the regulation proposed by the U.S. Food and Drug Administration (FDA) entitled "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002."

IWLA is an international association of companies which provide public and contract warehousing and related logistics services. Public and contract warehousing represents \$78 billion of the \$910 billion logistics industry. Contract warehousing is the fastest growing segment of the logistics industry and is expected to grow at a rate of 20 percent over the next seven years. Public warehousing is also expected to grow by a rate of 6 to 8 percent during that time.

The FDA has erred in its cost assumptions in the proposal by:

1. Significantly underestimating the number of public warehouses affected by the rule; and
2. Inaccurately assessing the compliance costs for warehouses as a result of combining wholesalers and warehouses for purpose of the analysis.

FDA Has Underestimated the Number of Public Warehouses Affected

FDA uses as the primary source for the number of warehouses "the 2000 CBP and 1999 Nonemployer Statistics for the NAICS codes identified in Table 1 of this document." [68 FR 25202]

02N-0277

C31

The applicable portion of the referenced Table 1 is included below:

TABLE 1.—AFFECTED FACILITY AND FIRM DETAILS

Type	Facility Estimate	Facility to Firm Adjust. Factor	Firm Estimate	North American Industry Classification System (NAICS) Codes if Applicable
<i>Domestic</i>				
Manufacturers	43,376	1.17	36,948	3111–3119, 3121
Wholesalers/Warehouses	95,745	1.24	76,952	4224, 4225, 4228, 49312, 49313
Restaurants	73,812	1.07	69,387	5511, 5512, 5514, 5515, 5516, 5517, 5518, 5519

The North American Industry Classification System (NAICS) codes used in the table above for warehouses are:

49312 – Refrigerated Warehousing and Storage

49313 – Farm Product Warehousing and Storage

Not included is the NAICS code 49311 – General Warehousing and Storage. A significant number of food grade public warehouses, possibly the majority, subject to this rule would be included in 49311 rather than in the other NAICS codes. IWLA has polled a number of its larger members, and in almost every case, they are classified in 49311. As such, FDA's estimate that a total of 76,952 wholesaler and public warehouse companies are affected by the proposal is greatly understated. FDA should review and recalculate the number of public warehouses affected prior to issuing the final rule.

FDA May Have Inaccurately Assessed the Burden on Warehouses

The estimated cost per facility or per firm in the public warehousing industry is likely to be in error because of the apparent assumption that costs incurred would be similar for both a wholesaler and a public warehouse. The costs studied by FDA include additional record information; information collection and maintenance, storage time, and records access time. Throughout the *Analysis of Economic Impact*, warehousing and wholesaling are treated as like industries, as indicated in Table 3 [68FR 25206] and Table 5 [68 FR 25210].

TABLE 3.—LEARNING COSTS

	Firm Count	Cost (at labor rate of \$25.10)	Average Learning Costs per Firm
<i>Domestic</i>			
Manufacturers	43,376	\$5,215,000	\$120
Wholesalers/Warehouses	95,745	\$11,511,000	\$120

TABLE 5.—ADDITIONAL RECORDS MAINTENANCE COSTS, OPTION 2

	Facility Count	Cost	Average Cost per Firm
Manufacturers	43,376	\$14,154,000	\$383
Wholesalers/Warehouses	95,745	\$31,242,000	\$406

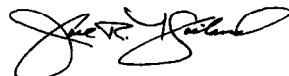
In fact, there are significant differences between a wholesaler and a public warehouse operator. The primary difference is that the wholesaler owns the product and the warehouse does not. The main costs associated with compliance are the costs that will be incurred with keeping records as to the immediate previous source and the immediate subsequent recipient. The wholesaler is in a much better position to capture this information in a less costly manner than is the warehouse operator. The wholesaler executes a business transaction when it purchases a product and when it subsequently sells the product. In simplest terms, the wholesaler knows the seller and the purchaser, e.g. the immediate source and immediate subsequent recipient, because he is part of the ownership chain. The warehouse, however, is a third-party provider of warehousing, storage and other value-added services, e.g., labeling. The warehouse does not purchase the product and therefore does not have direct knowledge of where the product originates; and the warehouse does not sell the product, but simply prepares the product for transport, and, therefore, may not have direct knowledge of the product's next destination.

Another distinction is the product velocity and diversity between the wholesaler and the warehouse. A public warehouse provides short-term storage on a month-to-month basis and the contract warehouse provides long term storage, based on minimum pallet positions or minimum square footage. The product mix in the warehouse is constantly changing based on the needs and wishes of the product owner. The wholesaler, however, because of the nature of that business, will handle a more defined set of food products over a longer period of time.

We urge the FDA to reopen the *Economic Analysis* in order to properly determine the cost burdens of compliance with the rule by public warehouses.

Thank you for your consideration of these comments.

Sincerely,



JOEL R. HOILAND
President and CEO

cc: Dockets Management Branch
(HFA-305),
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852.